

CLAIMS:

Accordingly, what is claimed is:

5 1. A centrifugation configuration for centrifugally separating a composite fluid into
component parts thereof, said configuration comprising:
a rotor which includes;
a composite fluid containment area;
a fluid inlet channel;
10 a peripheral fluid separation channel;
first and second separated component outlet channels; and
first and second separated component collection areas;
wherein said inlet channel is disposed in fluid communication with said fluid containment
area; and wherein said peripheral separation channel is disposed in fluid communication with
15 said fluid inlet channel and said first and second separated fluid outlet channels; and wherein said
first and second separated fluid outlet channels are disposed in fluid communication with said
first and second separated component collection areas; and
whereby said first and second separated fluid outlet channels also have respective first
and second heights wherein said heights are related to each other so as to provide a substantial
20 fluid pressure balance for respective separated components flowing therethrough.

2. A centrifugation configuration according to Claim 1 in which the relationship of the
respective first and second heights of said first and second separated component outlet channels
to each other which provides the substantial fluid pressure balance for respective separated
25 components flowing through the respective first and second outlet channels, is defined such that
it controls the interface of separated components within the peripheral separation channel.

3. A centrifugation configuration according to Claim 1 in which the relationship of the respective first and second heights of said first and second separated component outlet channels to each other which provides the substantial fluid pressure balance for respective separated components flowing through the respective first and second outlet channels, is defined as

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$$\rho_2 g_2 h_2 = \rho_3 g_3 h_3 \quad ;$$

wherein the first height of the first outlet channel is h_2 , and the second height of the second outlet channel is h_3 , wherein g_2 and g_3 are centrifugal acceleration values and ρ_2 represents the density of the separated component in the first outlet channel and ρ_3 represents the density of the separated component in the second outlet channel.

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4. A centrifugation configuration according to Claim 3 wherein the outlet ρ value, in $\rho_2 g_2 h_2$, includes first and second elements from the first component and the second component, such that $\rho_2 g_2 h_2$ is the sum of $\rho_{1st\ component} g_{1st\ component} (h_2 - h_i)$ and $\rho_{2nd\ component} g_{2nd\ component} h_i$; wherein h_i is the height of the interface between the first and second separated fluid components.

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5. A centrifugation configuration according to Claim 4 wherein the second separated component is a heavier phase component.

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6. A centrifugation configuration according to Claim 3 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first separated component ρ value, in $\rho_2 g_2 h_2$, and the second separated component ρ value, appearing in $\rho_3 g_3 h_3$, represent the respective densities of the separated components of blood including plasma and red blood cells (RBCs).

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7. A centrifugation configuration according to Claim 6 wherein the second ρ value, in $\rho_2 g_2 h_2$, includes both a plasma and an RBC component, such that $\rho_2 g_2 h_2$ is the sum of $\rho_{RBC} g_{RBC} h_i$ and $\rho_{plasma} g_{plasma} (h_2 - h_i)$; wherein h_i is the height of the interface between the RBCs and the plasma.

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8. A centrifugation configuration according to Claim 1 in which the relationship of the respective first and second heights of said first and second separated component outlet channels and the height of the inlet channel to each other which provides a fluid pressure driving force for driving the composite fluid through the separation channel and for flowing the respective separated components through the respective first and second outlet channels, is defined such that it controls the driving force of composite fluid and the separated components within the peripheral separation channel.

9. A centrifugation configuration according to Claim 1 wherein the height of the inlet channel is designated as h_1 and wherein the first height of the first outlet channel is h_2 , and the second height of the second outlet channel is h_3 , wherein g_1 , g_2 and g_3 are centrifugal values and ρ_1 represents the density of the fluid in the fluid inlet channel, ρ_2 represents the density of the separated components in the first outlet channel, and ρ_3 represents the density of the separated components in the second outlet channel and these values are related to each other such that the rotor inlet fluid dynamic pressure, $\rho_1 g_1 h_1$, is greater than either of the two outlet fluid dynamic pressures, $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, or

$$\rho_1 g_1 h_1 > \rho_2 g_2 h_2 \text{ or } \rho_1 g_1 h_1 > \rho_3 g_3 h_3$$

so that fluid will flow from the rotor inlet toward the outlets.

10. A centrifugation configuration according to Claim 9 wherein the ρ values are different for each term in the relationship such that the inlet ρ value, in $\rho_1 g_1 h_1$, is the density of the inlet composite fluid to be separated, whereas, the outlet ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of the respective separated fluid components.

11. A centrifugation configuration according to Claim 10 wherein the inlet ρ value, in $\rho_1 g_1 h_1$, includes first and second elements from the composite fluid and the first separated component, such that $\rho_1 g_1 h_1$ is the sum of $\rho_{\text{composite fluid}} g_1 (h_1 - h_i)$ and $\rho_{\text{1st component}} g_{\text{1st component}} h_i$; wherein h_i is the height of the interface between the first and second separated fluid components.

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12. A centrifugation configuration according to Claim 11 wherein the first separated component is a heavier phase component.

13. A centrifugation configuration according to Claim 9 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of whole blood, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of the separated components, plasma and red blood cells (RBCs).

14. A centrifugation configuration according to Claim 13 wherein the first ρ value, in $\rho_1 g_1 h_1$, includes both a whole blood and an RBC component, such that $\rho_1 g_1 h_1$ is the sum of $\rho_{\text{RBC}} g_{\text{RBC}} h_i$ and $\rho_{\text{wholeblood}} g_{\text{wholeblood}} (h_1 - h_i)$; wherein h_i is the height of the interface between the RBCs and the plasma.

15. A centrifugation configuration according to Claim 9 in which the ρ_1 value in the $\rho_1 g_1 h_1$ term has two distinct components derived from the combination of discrete fluid pressure terms such that $\rho_1 g_1 h_1$ is the sum of a $\rho_{\text{1st component}} g_{\text{1st component}} h_i$ and a $\rho_{\text{composite fluid}} g_1 (h_1 - h_i)$; whereby h_i is the height of the interface between the first and second separated components, and,

$$\rho_1 g_1 h_1 = \rho_{\text{1st component}} g_{\text{1st component}} h_i + \rho_{\text{composite fluid}} g_1 (h_1 - h_i) > \rho_{\text{1st component}} g_3 h_3 = \rho_3 g_3 h_3.$$

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16. A centrifugation configuration according to Claim 9 in which the composite fluid to be separated is blood and the separated components are red blood cells (RBCs) and plasma, and wherein the ρ_1 value in the $\rho_1 g_1 h_1$ term has two distinct components derived from the combination of discrete fluid pressure terms, thus having an RBC and a whole blood component such that $\rho_1 g_1 h_1$ is the sum of a $\rho_{RBC} g_3 h_i$ and a $\rho_{whole\ blood} g_1 (h_1 - h_i)$; wherein h_i is the height of the interface between the RBCs and the plasma, and,

$$\rho_1 g_1 h_1 = \rho_{RBC} g_3 h_i + \rho_{whole\ blood} g_1 (h_1 - h_i) > \rho_{RBC} g_3 h_3 = \rho_3 g_3 h_3.$$

17. A centrifugation configuration for centrifugally separating a composite fluid into component parts thereof, said configuration comprising:

a rotor which includes;

a composite fluid containment area;

a fluid inlet channel;

a peripheral fluid separation channel;

first and second separated fluid outlet channels, and

first and second separated component collection areas;

wherein said inlet channel is disposed in fluid communication with said fluid containment area; and wherein said peripheral separation channel is disposed in fluid communication with said fluid inlet channel and said first and second separated fluid outlet channels; and wherein said first and second separated fluid outlet channels are disposed in fluid communication with said first and second separated component collection areas; and

whereby said first and second separated fluid outlet channels and said fluid inlet channel also have respective first, second and third heights wherein said heights are related to each other so as to provide a fluid pressure forward flow drive force for respective composite fluid and the respective separated components flowing therethrough.

18. A centrifugation configuration according to Claim 17 in which the relationship of the respective first and second heights of said first and second separated component outlet channels and the height of the inlet channel to each other which provides the fluid pressure driving force for driving the composite fluid into the separation channel and flowing the respective separated components through the respective first and second outlet channels, is defined such that it controls the driving force of composite fluid and the separated components through the separation channel.

19. A centrifugation configuration according to Claim 17 in which the relationship of the respective first and second heights of said first and second separated component outlet channels and the height of the inlet channel to each other which provides a fluid pressure driving force for driving the composite fluid into the separation channel and flowing the respective separated components through the respective first and second outlet channels, is defined such that it controls the driving force of composite fluid and the separated components within the peripheral separation channel.

20. A centrifugation configuration according to Claim 17 wherein the height of the inlet channel is designated as h_1 and wherein the first height of the first outlet channel is h_2 , and the second height of the second outlet channel is h_3 , wherein g_1 , g_2 and g_3 are centrifugal values and ρ_1 represents the density of the fluid in the fluid inlet channel, ρ_2 represents the density of the separated component in the first outlet channel, and ρ_3 represents the density of the separated component in the second outlet channel and these values are related to each other such that the rotor inlet fluid dynamic pressure, $\rho_1 g_1 h_1$, is greater than either of the two outlet fluid dynamic pressures, $\rho_2 g_2 h_2$ or $\rho_3 g_3 h_3$, or

$$\rho_1 g_1 h_1 > \rho_2 g_2 h_2 \text{ or } \rho_3 g_3 h_3$$

so that fluid will flow from the rotor inlet toward the outlets.

21. A centrifugation configuration according to Claim 20 wherein the ρ values are different for each term in the relationship such that the inlet ρ value, in $\rho_1 g_1 h_1$, is the density of the inlet composite fluid to be separated, whereas, the outlet ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of the respective separated fluid components.

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22. A centrifugation configuration according to Claim 21 wherein the inlet ρ value, in $\rho_1 g_1 h_1$, includes first and second elements from the composite fluid and the first separated component, such that $\rho_1 g_1 h_1$ is the sum of $\rho_{\text{composite fluid}} g_1 (h_1 - h_i)$ and $\rho_{\text{1st component}} g_{\text{1st component}} h_i$; wherein h_i is the height of the interface between the first and second separated fluid components.

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23. A centrifugation configuration according to Claim 20 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of whole blood, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of the separated components, plasma and red blood cells (RBCs).

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24. A centrifugation configuration according to Claim 23 wherein the second ρ value, in $\rho_2 g_2 h_2$, includes both a plasma and an RBC component, such that $\rho_2 g_2 h_2$ is the sum of $\rho_{\text{RBC}} g_{\text{RBC}} h_i$ and $\rho_{\text{plasma}} g_{\text{plasma}} (h_2 - h_i)$; wherein h_i is the height of the interface between the RBCs and the plasma.

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25. A centrifugation configuration according to Claim 20 in which the ρ_1 value in the $\rho_1 g_1 h_1$ term has two distinct components derived from the combination of discrete fluid pressure terms such that $\rho_1 g_1 h_1$ is the sum of a $\rho_{\text{1st component}} g_{\text{1st component}} h_i$ and a $\rho_{\text{composite fluid}} g_1 (h_1 - h_i)$; whereby h_i is the height of the interface between the first and second separated components, and,

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$$\begin{aligned} \rho_1 g_1 h_1 &= \rho_{\text{1st component}} g_{\text{1st component}} h_i + \rho_{\text{composite fluid}} g_1 (h_1 - h_i) > \rho_{\text{1st component}} g_{\text{1st component}} h_2 \\ &= \rho_2 g_2 h_2. \end{aligned}$$

26. A centrifugation configuration according to Claim 20 in which the composite fluid to be separated is blood and the separated components are red blood cells (RBCs) and plasma, and wherein the ρ_1 value in the $\rho_1 g_1 h_1$ term has two distinct components derived from the combination of discrete fluid pressure terms thus having an RBC and a whole blood component such that $\rho_1 g_1 h_1$ is the sum of a $\rho_{RBC} g_{RBC} h_i$ and a $\rho_{whole\ blood} g_{whole\ blood} (h_1 - h_i)$; wherein h_i is the height of the interface between the RBCs and the plasma, and,

$$\rho_1 g_1 h_1 = \rho_{RBC} g_{RBC} h_i + \rho_{whole\ blood} g_{whole\ blood} (h_1 - h_i) > \rho_{RBC} g_{RBC} h_3 = \rho_3 g_3 h_3.$$

27. A centrifugation configuration according to Claim 17 whereby the respective first and second heights of said first and second separated component outlet channels are related to each other so as to provide a substantial fluid pressure balance for respective separated components flowing therethrough.

28. A centrifugation configuration according to Claim 27 in which the relationship of the respective first and second heights of said first and second separated component outlet channels to each other which provides the substantial fluid pressure balance for respective separated components flowing through the respective first and second outlet channels, is defined such that it controls the interface of separated components within the peripheral separation channel.

29. A centrifugation configuration according to Claim 27 in which the relationship of the respective first and second heights of said first and second separated component outlet channels to each other which provides the substantial fluid pressure balance for respective separated components flowing through the respective first and second outlet channels, is defined as

$$\rho_2 g_2 h_2 = \rho_3 g_3 h_3 ;$$

wherein the first height of the first outlet channel is h_2 , and the second height of the second outlet channel is h_3 , wherein g_2 and g_3 are centrifugal acceleration values and ρ_2 represents the density of the separated components in the first outlet channel and ρ_3 represents the density of the separated components in the second outlet channel.

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30. A centrifugation configuration according to Claim 27 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first separated component ρ value, in $\rho_2 g_2 h_2$, and the second separated component ρ value, appearing in $\rho_3 g_3 h_3$, represent the densities of the separated components, plasma and red blood cells (RBCs).

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31. A centrifugal separation device for use in a fluid separation system to centrifugally separate a composite fluid into composite components thereof, said centrifugal separation device comprising:

a centrifugal drive motor base;

a centrifugal rotor housing which is adapted to be disposed in an operable rotor-driving position on said centrifugal drive motor base, and;

a rotor disposed in a freely rotatable position within said housing, said rotor having:

a composite fluid containment area and at least one component fluid collection area;

said rotor also having a fluid inlet channel;

a circumferential fluid separation channel and first and second separated fluid outlet channels;

wherein said inlet channel is disposed in fluid communication with said fluid containment area; and

wherein said circumferential separation channel is disposed in fluid communication with said fluid inlet channel and said first and second separated fluid outlet channels; and

wherein at least one of said first and second separated fluid outlet channels also being disposed in fluid communication with said at least one component fluid collection area;

said first and second fluid outlet channels also having respective first and second heights wherein said heights are related to each other so as to provide a substantial fluid pressure balance for respective component fluids flowing therethrough.

5 32. A centrifugal separation device according to Claim 31 in which the centrifugal drive motor base produces a rotating magnetic field, and wherein said rotor contains a magnetically reactive material which is adapted to rotate with the rotating magnetic field produced by said motor base, whereby said rotor is caused to rotate by the co-action of said magnetically reactive material and said rotating magnetic field.

10 33. A centrifugal separation device according to Claim 31 in which the centrifugal drive motor base has a flat top surface, and the rotor housing has a flat bottomed surface, whereby the flat top surface of the drive motor base and the flat bottomed surface of the rotor housing co-act to provide the adaptation of the rotor housing to be disposed in operable rotor-driving position on
15 said centrifugal drive motor base.

20 34. A composite fluid separation device comprising:
a rotor having an axial, a radial and a circumferential orientation; wherein said rotor has a circumference and is rotatable about said axial orientation;

said rotor also having:

- a substantially centrally-disposed containment pocket;
- an inlet channel communicating with said containment pocket;
- a peripheral channel communicating with said inlet channel;
- an outlet channel communicating with said peripheral channel; and
- 25 a collection pocket communicating with said outlet channel;

whereby said inlet channel has a representative height h_c and the outlet channel has a representative height h_1 ; and

height h_c and height h_1 are related to each other such that

30 $h_c > h_1 .$

35. A composite fluid separation device according to Claim 34 in which said rotor further comprises:

a second outlet channel communicating with said peripheral channel; and

a second collection pocket communicating with said second outlet channel;

whereby said second outlet channel has a representative height h_2 ; and

whereby the height h_c and the heights h_1 and h_2 are related to each other such that

$$h_c > h_1 \text{ or } h_2 .$$

36. A composite fluid separation device according to Claim 34 in which said rotor further comprises:

a second outlet channel communicating with said peripheral channel; and

a second collection pocket communicating with said second outlet channel;

whereby said second outlet channel has a representative height h_2 ; and

whereby the heights h_1 and h_2 are related to each other such that

$$h_1 = h_2 .$$

37. A disposable container system for use in the separation of a composite fluid into separated components, using a disparate rotor which is adapted to receive the disposable container system, the disposable container system comprising:

a composite fluid container;

a first separated component container; and

a separation vessel;

whereby said composite fluid container is connected to said separation vessel by an inlet line, and said first separated component container is connected to said separation vessel by a first outlet line.

38. A disposable container system according to Claim 37 in which the composite fluid container is connected to an access line which may be used to connect the system to a donor/patient.

5 39. A disposable container system according to Claim 37 which further comprises a second separated component container; and
whereby said second separated component container is connected to said separation vessel by a second outlet line.

10 40. A disposable container system according to Claim 37 in which at least one of said containers includes an access port structure.

15 41. A disposable container system according to Claim 37 in which at least one of said containers includes an air vent structure.

 42. A disposable container system according to Claim 37 in which at least one of said containers includes a frangible flow stoppage structure.

20 43. A disposable container system according to Claim 37 in which at least one of said connecting lines includes a flow stoppage device.

 44. A disposable container system according to Claim 37 in which at least one of said containers is a bag constructed of flexible materials.

25 45. A disposable container system according to Claim 44 in which at least one of said containers is a bag constructed from flexible plastic sheets.

 46. A disposable container system according to Claim 37 in which at least one of said connecting lines is a tubing line constructed of flexible materials.

47. A disposable container system according to Claim 46 in which at least one of said connecting lines is a tubing line constructed of extruded plasticized materials.

48. A disposable container system according to Claim 37 in which said vessel is constructed of flexible materials.

49. A disposable container system according to Claim 48 in which said vessel is a bag constructed from flexible plastic sheets.

50. A disposable container system according to Claim 37 in which said vessel is constructed of resilient materials.

51. A disposable container system according to Claim 50 in which said vessel is constructed from injection-molded plastic.

52. A disposable container system according to Claim 50 in which said vessel is constructed from blow-molded plastic.

53. A disposable container system according to Claim 37 in which said vessel is a tubing line constructed of flexible materials.

54. A disposable container system according to Claim 53 in which said vessel is a tubing line constructed of extruded plasticized materials.

55. A method for separating a composite fluid into component parts comprising:
providing a rotor configuration having:
a rotor which includes;
a composite fluid containment area;
a fluid inlet channel;
a peripheral fluid separation channel;

first and second separated fluid outlet channels; and

first and second separated component collection areas;

wherein said inlet channel is disposed in fluid communication with said fluid containment area; and wherein said peripheral separation channel is disposed in fluid communication with

5 said fluid inlet channel and said first and second separated fluid outlet channels; and wherein said first and second separated fluid outlet channels are disposed in fluid communication with said first and second separated component collection areas; and

whereby said inlet channel and said first and second separated fluid outlet channels also have respective inlet and first and second outlet heights wherein said heights are related to each
10 other so as to provide a substantial fluid pressure flow control for respective composite and separated components flowing therethrough; and

loading a composite fluid into the composite fluid containment area of said rotor configuration; and

rotating said rotor configuration to separate said composite fluid into its component parts.

15 56. A method according to Claim 55 which further includes collecting said separated components.

57. A method according to Claim 55 which further includes automatically driving the
20 flow through said separation channel.

58. A method according to Claim 55 which further includes automatically shutting off the flow through said separation channel.

25 59. A method according to Claim 55 which further includes automatically readjusting the flow in and through said separation channel by automatically equalizing fluid pressure in the first and second separated fluid outlet channels.

60. A method according to Claim 55 which further includes which further includes collecting said separated components and clamping the flow out of said separation channel prior to said step of collecting said separated components.

5 61. A method according to Claim 60 which further includes automatically centrifugally clamping the flow out of said separation channel until a preselected rotational speed is achieved.

10 62. A method according to Claim 60 which further includes automatically centrifugally clamping the flow out of said separation channel after collection of said separated components when a preselected rotational speed is no longer achieved.

15 63. A method according to Claim 60 which further includes automatically capturing an intermediate phase component in said separation channel by clamping the flow out of said separation channel after collection of said first and second separated components when a preselected rotational speed is no longer achieved.

 64. A method according to Claim 55 which further includes: using a disposable bag and tubing set within said rotor configuration.